Town Hall: Stakeholder Feedback on Proposed LAC Caregiver Legislation
March 28, 2014

Background
In response to findings from the Medical Marijuana Audit published in June 2013, the Colorado Department of Public Health and Environment (CDPHE) worked with members of the Legislative Audit Committee (LAC) to draft a bill to address the following findings and recommendations from the State Auditor's Office:

- Recommendation #4, page 53, Strengthen the oversight of caregivers by:
  (a) implementing procedures to ensure that caregivers meet all legal requirements;
  (b) approving waivers for caregivers to serve more than five patients only when exceptional circumstances exist; and
  (c) working with Revenue to determine whether additional criteria are needed to differentiate caregivers from businesses, implement methods to determine whether an individual is a caregiver or a business, and work with the General Assembly as necessary to implement any proposed changes.
- Recommendation #5, page 55, Work with Department of Revenue and stakeholders to:
  (a) evaluate the need to continue to collect information on which caregivers have been designated by individuals as their providers and ensuring any information maintained is updated and accurate; and
  (b) determine whether Public Health or Revenue needs greater statutory authority to effectively regulate caregivers and if so, present proposed changes to the General Assembly as necessary.
- Recommendation #6, page 69, Ensure the confidentiality of the Medical Marijuana Registry by: (a) seeking guidance from the Attorney General on what constitutes an "authorized employee" who can be given access to the Registry and work with the General Assembly if needed to define "authorized employee" in statute;

A copy of the current bill language can be found on the department's Medical Marijuana website.

A Town Hall meeting was held on Friday, April 28, 2014 to provide a forum for stakeholders to provide public comment on the proposed legislation. The following document summarizes the stakeholder comments provided during the Town Hall meeting by common themes along with responses from, and future action items for, the Colorado Department of Public Health and Environment (CDPHE).

Public comments start at 1:27 pm

Topic #1 Caregiver Model, Role, and Relationship to Medical Marijuana Dispensaries

Caregiver Model and Role
- Don't penalize patients and caregivers based on a few bad actors

- Caregivers wouldn't knowingly give their name and information on their plant count to the state if they wanted to do something illegal
- Caregivers don't want to turn terminal patients away
- The diversion of drugs for illegal use can be found on craigslist, not through caregivers
- Caregivers should be investigated if the department suspects foul play
- In determining waiver, CDPHE may consider excess patients for caregivers– this legislation is just removing the department's ability to make this decision
- For patients that are not capable of growing plants on their own, caregivers are farmers. It takes a special skill to grow specific strains for specific patients
- Some patients are not satisfied with dispensaries, they feel caregivers provide a better product/service

Response:
CDPHE recognizes the vast majority of patients and caregivers are abiding by the current medical marijuana laws. Based on January 2014 data, of the 3,330 registered caregivers in the registry, only 24 are serving more than 5 patients (the current statutory patient limit for caregivers without an "exceptional circumstance" waiver provided by CDPHE). The proposed legislation to limit caregivers to serving no more than 5 patients will only impact those 24 caregivers that are currently serving more than 5 patients.

The Colorado Constitution defines caregivers as individuals who have "significant responsibility for managing the well-being of a patient who has a debilitating medical condition" [Article XVIII, section 14(1)(f)]. State regulations further establish that "the relationship between a primary caregiver and patient is to be a significant relationship that is more than provision of medical marijuana or medical marijuana paraphernalia. Services beyond the provision of medical marijuana that may be provided by the primary caregiver include, but shall not be limited to, transportation or housekeeping or meal preparation or shopping or making arrangements for access to medical care or other services unrelated to medical marijuana. If patients do not require caregiver service other than the provision of medical marijuana, then the patients shall not designate a primary caregiver." (5 CCR 1006-2).

Of those 24 caregivers that exceed the 5 patient statutory limit, the highest number of patients served by one caregiver is 82. At 82 patients, a caregiver cannot meet the constitutional and statutory requirement to have significant responsibility for managing the well-being of a patient with a debilitating medical condition. One could also argue that this is no longer within the caregiver model, but in fact is a small, unlicensed marijuana business.

Additionally, the creation of tinctures and other marijuana derivative products implicates safety issues, as demonstrated by problems associated with some home grows causing structural damage to the homes and the surrounding community. Such operations should be conducted in a licensed facility with appropriate regulatory oversight.

Based on stakeholder feedback, the department is going to enhance its policies and procedures for reviewing and approving waivers for caregivers to serve more than five patients. The department will develop more specific criteria for what constitutes "exceptional circumstances".

Caregivers vs. Dispensaries

- The number of caregivers dropped significantly after the passage of HB-10-1284 , which established the dispensary model in Colorado
- Small communities are going to be overrun with large dispensary businesses if caregivers are limited in numbers of patients served and plants provided per patient, leading to shutting down more caregiver operations
- Certain caregivers in cities/counties that ban dispensaries cannot become a dispensary, but if laws should change, the chances of becoming a dispensary are reduced with a 6 patient limit

Response:
Caregivers are required to register with the Department of Revenue (DOR) [CRS 25-1.5-106(7)(e)], although many do not. According to the audit, as of March 2013, only 28 caregivers had registered their grow locations with the DOR, which represents less than one percent of the caregivers in the registry.

Large marijuana grows should be defined as marijuana businesses, where regulations can control health, safety, and trafficking issues. As discussed during the town hall meeting, the federal government will be less likely to intervene in Colorado's medical marijuana program if Colorado has measures in place to prevent the diversion of marijuana outside of the regulated system and prevent the illicit marijuana trade that funds criminal enterprises - both of which are possible without addressing the current caregiver model.

Topic #2: Access Issues - Financial and Geographical (Proximity to a Dispensary)

Access Issues

- Rural communities do not have access to dispensaries
    - Some patients must drive up to 120 miles to get to a dispensary;
    - There is no access to dispensaries in places like the western slope
- Many patients can't or won't drive, caregivers provide transportation to dispensaries

Response:
Caregivers can legally operate throughout the state, even within local jurisdictions that have exercised their authority under Section 12-43.3-106, C.R.S., to prohibit medical marijuana businesses.

A patient who designates a caregiver cannot also purchase medical marijuana from a dispensary, unless the patient is homebound and has obtained Public Health's approval for his or her designated caregiver to purchase and transport medical marijuana from a dispensary on the patient's behalf [Sections 25-1.5-106(8)(f), C.R.S., and 25-1.5-106(9)(e), C.R.S.].

Cost and Insurance

- Supply low-income patients access to medication, not for profit, patients don't have free, easy, access to cannabis due to restraints (like these) and costs
- This law is designed to allow dispensaries to make money, dispensaries are charging too much
- There is no medical insurance that supports medical marijuana as an alternative treatment; all costs are out of pocket and dispensary costs are increasing
- Many patients don't have medical insurance and won't be able to get access to medical records
- Many patients can't afford recreational marijuana due to prohibitive costs
- Pass a bill to give insurance access to those that can't afford medical marijuana; create an indigent patient fund

Response:
In terms of addressing costs associated with procuring medical marijuana, patients maintain the right to grow their own medical marijuana. Health insurance has not yet added medical marijuana as a benefit, but that may change in the future depending upon the expanding research knowledge we gain from marijuana studies, such as the Department's medical marijuana research grant program to study the efficacy of the use of medical marijuana for various conditions (see additional comments below).

Topic #3: Medical Necessity and Excess Plant/Ounce Counts

Medical Necessity

- Caregivers grow only those plants that their patient(s) need
- The allowable number of plants per patient should be left up to the individual's recommending physician
- This is a recommendation, not a prescription. Physicians don't get enough feedback when they only see patients once a year. There is a conference scheduled in September to discuss this issue.
- The MMR red card is voluntary – the department is only responsible for issuing the card, not judging the doctor-patient relationship
- There is a need for excess plants in order to develop certain cannabis products such as oils, tinctures, juices, etc.
- Not all plant strains produce the same quantities of marijuana, not all strains provide the same medicinal effects
- Stakeholders stated there are hundreds of studies to show the need for elevated plant counts.
- Constitution can't be changed in regard to excess plant count
- The limit of 6 plants per patient is arbitrary and capricious
- Regulators do not issue laws to limit the use of narcotics prescribed, why are physicians that over-prescribe narcotics not held responsible?

Response:
Patients have the right to receive the community standard of care when it comes to monitoring medical marijuana for efficacy and safety. The default standard set in the constitutional of 6 plants and 2 ounces of medical marijuana for a patient will be input into the registry for each patient whose application has been approved, unless the patient's physician demonstrates the patient's medical need for excess plants and/or ounces. This creates an equitable, enforceable model which strengthens the efficacy of medical marijuana use and enhances patient safety moving forward.

Those physicians that appear to be 'over-prescribing' medical marijuana will be held to the same standards as other healthcare providers who do not follow the appropriate standard of care, such as those physicians who over-prescribe narcotics. In either circumstance, these physicians can be referred to the Colorado Medical Board for investigation.

During discussions with various patients, physicians, and industry leaders, Dr. Wolk did not find evidence demonstrating the need for excess plant counts to produce specific tinctures, edibles and other cannabis products. This is not to say that there is not a need; however, no scientific evidence has been provided to date that demonstrates the medical need to possess more than the constitutional standard of 6 plants and 2 ounces.

Dr. Wolk encourages stakeholders to provide peer-reviewed studies and other documentation to the department for review. Until more scientific evidence is available, the department will require recommending physicians to provide documentation of medical necessity for all recommendations in excess of the constitutional 6 plant and 2 ounce standard.

If medical necessity is not evident, CDPHE will still approve the application (presuming all other application criteria are met); however, the patient's record in the registry will be adjusted to the constitutional standard amount rather than the increased physician-recommended amount.

The patient or his or her primary caregiver may still raise as an affirmative defense in a court of law to demonstrate that greater plant/ounce amounts were medically necessary to address the patient's debilitating medical condition.

HIPAA violation

- Is the requirement to submit medical records to the CDPHE for the review of medical necessity a violation of HIPAA?

Response:
No, it is the patient's choice whether to supply CDPHE with medical records demonstrating medical necessity. Patients are not required to submit their medical records to CDPHE in order to be approved for the constitutional standard of 6 plants and 2 ounces of medical marijuana and the patient still has the option to prove that he/she was entitled to an increased plant count as an affirmative defense in a criminal case.

In the event that the patient would like the medical marijuana registry to reflect a plant/ounce count in excess of the constitutional standard, the patient may choose to allow his/her physician to submit the patient's medical records to the department, thereby waiving HIPAA protections. The department is acting in its role as a health oversight agency under HIPAA, and disclosure of patient records to a health oversight agency does not require patient consent under HIPAA. 45 C.F.R. 164.512(d).

CDPHE will continue to operate under the confidentiality requirements as outlined under Article XVIII, section 14 of the Colorado Constitution, ensuring medical marijuana patient information remains secure.

Research Bill

- There are diseases that need an elevated plant count, different amounts are needed to make different medicine based on the type of condition
- More education and more information from testing is needed
- Medical marijuana should be approved for PTSD and other medical conditions
- Use research from National Institutes of Health (NIH)
- The state of Washington maintains 24 plants per patient – research has found that on average patients need 24-30 plants to treat conditions
- Cannabis has no known lethal dose
- Use money to do research and provide education - how much of the cash fund will be used for this purpose?

Response:
Much is unknown about the potency and dosing of marijuana; more information is needed to further understand potential therapeutic uses of marijuana. That is why the recently proposed Senate Bill 14-155 to create a medical marijuana research grant program will be of such value in finding answers to these unknown questions.

Using up to $10 million of the medical marijuana program cash fund, the department will be able to support additional medical research on the potential therapeutic benefits of marijuana to:

- Add new debilitating medical conditions to Colorado's medical marijuana law; and
- Help physicians better understand the biochemical effects of prescribed medical marijuana;
- Further advance other state-funded medical marijuana research programs, such as in California, that have advanced the scientific knowledge about how marijuana works and methods to ensure appropriate dosing.
- Conduct observational trials that have the possibility of leading to clinical trials with changes from the federal government; and
- Conduct further research into the development of new strains of marijuana that appear to have promising therapeutic effects.

Topic #4: Stakeholder Engagement and Communication

Stakeholder Process

- CDPHE needs to have a transparent stakeholder process
- Leadership should understand the historical nature of the MMR program before making decisions
- Marijuana advocates in Colorado are a tight knit community and patients know how to access them
- Patients and caregivers should be notified about meetings by email and with more advanced notice
- There needs to be cooperation between law enforcement and the caregiver and medical marijuana community to get the laws right
- The current model puts law enforcement in a precarious situation

Response: CDPHE will be developing a stakeholder advisory committee over the next few months to bring together patients, physicians, caregivers, industry, law enforcement, Department of Revenue, the Attorney General's Office and other stakeholder representatives, as appropriate, to discuss relevant medical marijuana related issues. CDPHE staff support the development of a stakeholder process that will enable the department to obtain information and feedback in a constructive manner in order to support the maintenance and implementation of the medical marijuana registry into the future.

Currently, the medical marijuana patient application contains a field to collect patient and caregiver email addresses; however many patients do not provide this information on the application. In addition, there is no secure method in place to authenticate email addresses, which could lead to a breach of patient confidentiality, something the department takes very seriously. As a result of stakeholder feedback, the department will be testing the use of a new email listserv system to verify all email addresses that are provided to the registry. If successful, CDPHE will be able to provide email communications to those patients, caregivers, physicians and care centers who provide email addresses to the registry. This will be one more mechanism used to communicate with stakeholders in addition to the department website, the MMR blog, electronic newsletters and social media channels.

Topic #5: Defining Authorized Employees

Authorized Employees

- Perversion of laws to allow contractors to access registry
- Believe this policy is direct violation of constitution – department does not have authority to make these decisions
- Additional staff with access to record in registry is violation of my privacy

Response:

The auditors questioned whether the Department could provide access to the registry to contractors, as the Colorado Constitution refers to "authorized employees." The department sought legal advice from the Department of Law, and now seeks to clarify in statute the definition of an "authorized employee." Contractors provide valuable services to the registry

which allow the department to process applications within the 35 day review period designated in the Constitution. All contractors are currently required to sign and follow the same confidentiality agreements as department employees.

The draft legislation would enable the department to define "authorized employees of the state health agency" to include independent contractors employed to provide services to the medical marijuana program. For example, the Rocky Mountain Poison and Drug Center answers phone calls from patients with questions about the status of their card. This service has answered over 30,000 calls in the past year. This is a service that would otherwise not be available to patients without defining such contractors as an "authorized employee."

This language does not address access for law enforcement. This is a separate issue about which the Department is waiting to hear from the Attorney General.

Additional Topic for Legal Authority?

Legal Authority

- Why are opinions from the Attorney General's Office not shared with the public?
- CSA has exceptions, need to reference in regards to this law
- Must also abide by international treaty, controlled substances act, hemp exempt and any state that creates own regulatory program – no case law at Federal level
- Medical marijuana code will sunset in 2015, so if dispensaries are no longer authorized and caregivers are capped at 5 patients, this could create supply issues for patients

Response:
All state agencies receive legal advice and counsel from the Attorney General's Office, and just as in a private attorney-client relationship, that advice is attorney-client privileged and confidential. Regarding the legislative requirements for sunsetting programs, the Department of Revenue's Medical Marijuana Code will go through a sunset review before it's current repeal date of July 1, 2015. Concurrent with DOR's sunset review, the department's Medical Marijuana Program and the aspects of the medical marijuana program associated with the Colorado Medical Board are also required to be reviewed . Finally, the Medical Marijuana Program at the department's slated for repeal on July 1, 2019. Statutory changes made to any of these intertwined programs will likely require further regulatory action by any or all of the state agencies involved.

Public comment ended at 3:41 pm

Thank you to all of those individuals that provided comments either in writing or in person prior to or during the town hall meeting on Friday, April 28. The Department will work with the Legislature to determine if the draft bill language should be modified to address some of the caregiver and patient concerns outlined above. The Colorado Department of Public Health and Environment welcomes additional feedback and comments to be sent to cdphe.medicalmarijuana@state.co.us as decisions are made regarding next steps for this proposed legislation.